Piloting +Connection is Medicine / The Healing Spirits Program

IRB Version: 14 November, 2022

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JHSPH IRB Research Plan for New Data Collection
IRB Version: 18Jan2022

For new data collection, new data collection plus secondary data analysis, biospecimen repositories, and data coordinating center protocols.

DO NOT DELETE ANY QUESTIONS FROM THIS TEMPLATE

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Study Title: Piloting +Connection is Medicine / The Healing Spirits Program
IRB No.: 00020570
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I. <u>Aims of the Study</u>: *Describe the aims/objectives of the research and/or the project's research questions or hypotheses.*

This study aims to assess what benefit, if any, an individualized coping plan and facilitating connections to care through referral coordination in conjunction with culturally tailored caring messages, (herein called the +Connection is Medicine intervention (Navajo Nation study name; +CiM)/The Healing Spirits Program (White Mountain Apache Tribe Study Name; HSP) have on the mental health of American Indian (AI) youth and caregivers who were previously identified as having high levels of anxiety and depression as part of their participation in a Project SafeSchools cohort study (IRB No.: 14911). In addition, we will evaluate participant attitudes and beliefs regarding COVID-19 prevention strategies, testing, and vaccination. This pilot intervention will utilize a randomized controlled design, in which both the intervention and control groups receive individualized coping plans, facilitated connections to care, and COVID-19 safety messages. The intervention group also will receive regular caring messages.

Primary Aims:
Aim 1: Determine the effectiveness of +Connection is Medicine/The Healing Spirits Program (+CiM/HSP) on symptoms of depression and anxiety among caregivers and youth who have previously been identified as having elevated mental health symptoms, including recent suicidal ideation, identified through screening instruments administered as part of their participation in the Project SafeSchools cohort study (IRB #14911).

Hypothesis 1: Caregivers and youth who receive the additive culturally tailored text messages/postcards will demonstrate greater reductions in anxiety and depression symptom scores than those who only receive coping plans and case management.

Aim 2: Evaluate any benefit of individualized coping plans and check-ins on symptoms of depression and anxiety among caregivers and youth who have previously been identified as at risk through screening instruments administered as part of their participation in a Project SafeSchools cohort study using a within subjects design.

***Hypothesis 2*:** Caregivers and youth who receive a coping plan and check ins will demonstrate reduced symptoms of anxiety and depression compared to their previous assessments (leveraging data from assessments in Project SafeSchools cohort study).

Secondary Aim:
Secondary Aim 1: Assess participant views on COVID-19 prevention strategies (e.g., masking when sick, visiting a health care provider), testing, and vaccination.

II. <u>Background and Rationale</u>: *Explain why this study is being done. Summarize what is already known about the issue and reference previously published research, if relevant.*

<u>Epidemiology of Anxiety and Depression Among American Indians</u>
American Indians and Alaska Natives (AI/ANs) experience significant mental health disparities compared to other racial and ethnic groups in the United States (US). [1] Multiple forms of mental distress are often co-occurring in AI/AN communities and can increase the risk for suicidal behavior.[2,3,5] In 2019, suicide was

identified as the second highest cause of death for AI/ANs between the ages of 10 and 34.[3] In addition, several studies have found that Indigenous Historical Trauma (IHT)—defined as the intergenerational response to the loss of Indigenous lands, people, and culture due to contact and colonization—has negative intergenerational effects, including increased depressive symptoms, school delinquency, suicidal thoughts and behaviors, and substance use.[4] AI/AN youth in particular experience suicide rates 2.2 times higher than any race or age group.[5]

COVID-19 Pandemic

The COVID-19 pandemic has exacerbated mental health challenges among AI/ANs. Throughout the pandemic, AI/ANs have experienced some of the highest rates of COVID-19 disease and death in the US.[6,7] AI/ANs experienced more severe illness, with early estimates suggesting 4-5 times higher death rates than the general US population.[7] COVID-19 presents unique mental health and psychosocial health inequities for AI/AN families as well. The catastrophic history of infectious diseases, including those intentionally introduced as an act of genocide, underlies IHT that continues to impact AI/ANs today. While the COVID-19 pandemic is universal and global in its instillation of fear and anxiety, within the context of IHT, the physical and psychological threats of infectious diseases and the envisioned impacts on individuals, families, communities, and whole tribal nations are particularly acute. The collective memories of past trauma, during an ongoing pandemic that causes fear, anxiety, and social isolation, has the potential to further exacerbate existing mental health and psychosocial disparities across Indian Country.

Evidence-based approaches included in +CiM/ HSP (i.e., safety planning and Caring Contacts; +CiM/HSP)

All participants in the proposed study will be offered an adapted version of the Safety Planning Intervention (SPI). The SPI was developed by Barbara Stanley and Greg Brown and is a brief intervention that directly targets suicide risk with demonstrated efficacy, [and] is a recommended best practice for suicide prevention.[8-10] Similar interventions have been used for other safety issues, including domestic violence prevention.[11-12] The SPI aims to provide patients with an individualized set of steps that can be used progressively to both reduce risk and maintain safety when under particular stress. The SPI is conceptualized to target three proximal targets and underlying mechanisms of safety risk including increasing coping, decreasing access to lethal means, and increasing outpatient engagement. In the SPI, safety plans are developed collaboratively between providers, the at-risk individuals, and family members when possible. Stanley and Brown have also developed and tested an enhanced version of safety planning known as SPI+, which includes a series of brief telephone calls that focus on revising the safety plan and facilitating connections to care. For our work, we will adapt the SPI+ intervention to target a larger range of mental health distress by focusing on the increasing of coping resources and outpatient engagement components of the SPI+.

Half of the participants will be randomized to also receive the adapted Caring Contacts intervention. Caring Contacts is a cost and time effective suicide prevention intervention developed by a psychiatrist and World War II veteran and has been employed by serval organizations including the Veteran's Health Administration.[13-16] This simple intervention traditionally utilizes letters and postcards that are sent to an individual to remind them that they are cared about and that they matter. Letters may also include additional information about community resources available to the individual should they decide to engage or re-engage in mental health care. Research suggests that this intervention significantly reduces the likelihood of dying by suiciding and suicide attempt over a person's lifetime.[14-15] Similar approaches have been used to address underlying feelings of loneliness during the COVID-19 pandemic.[16] We also know from previous research that connectedness to family, community, and culture serves as a profound protective factor for AI/AN communities against mental health issues,[2, 4, 17] While there is an availability of resources within these communities such as crisis lines and access to mental and behavioral health services, access to care is particularly challenging given the rural setting and lack of culturally competent care, issues that have been exacerbated in the wake of COVID-19. A brief, and feasible intervention, such as Caring Contacts, has the potential to reach more individuals at risk and reduce the burden of mental health problems in the community. Recently, there has been an interest in

adapting this model to be used in other communities and with other modalities. As early as 2010 the use of Caring Contacts within text messages has shown high levels of acceptability and feasibility.[14-15] Additionally, cultural adaptations of this intervention have been made to components such as language used and delivery method.[13] By adapting Caring Contacts to align with Diné and White Mountain Apache cultures, it is our hope to harness the protective powers of community connection to reduce symptoms related to anxiety and depression.

The proposed study builds off our Community-Based Participatory Research process. As part of the parent study (Project SafeSchools) we have regularly met with our Community Advisory Boards (CABs) to provide updates on study progress and seek guidance on community need. Preliminary findings from the baseline time point have indicated a large and disproportionate burden of anxiety and depression. In response, the CABs as well as other stakeholders, have urged intervention. We are piloting +CiM/ HSP in response to these concerns and priorities in our partner communities.

III. Study Design:

A. *Provide a BRIEF overview of your study design and methods. The study design must relate to your stated aims/objectives. DETAILS WILL BE REQUESTED LATER. If your study also involves analysis of existing data, please complete Section XI, "Secondary Data Analysis of Existing Data" in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (JHSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens).*

We will conduct a Pilot Randomized Controlled Trial (RCT) among caregivers and youth (11-16 years old) who score at elevated risk of anxiety or depression. Participants will be recruited from the sample of individuals who have scored "at risk" on a mental health screening assessment tool in an ongoing cohort study, Project SafeSchools (IRB No.: 14911). All persons who screen "at risk" will be approached for this pilot study using our standardized recruitment script. Parent/Caregiver participants and youth participants may be enrolled separately. All potential study participants will be screened for eligibility after going through the consent/assent process. This is to confirm that potential participants are still presenting with elevated mental health scores at the start of enrollment. For parent/caregiver participants, the screening will utilize the same assessments as those used in the Project SafeSchools cohort study. All youth participants will complete a version of the brief screening tool as well. The screening tool plus a set of additional questions related to the interventions will be administered at 30 days post consent, and again at 90 days post consent to all participants. These additional assessments are needed to understand the immediate impact of the intervention approaches. Additional participant data from the Project SafeSchools study will be analyzed to better understand symptoms prior to the pilot study enrollment, and as a longer-term outcome assessment for the pilot study. If promising, the results of this study will inform a future fully powered study to test these interventions at scale.

B. *Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample, distinguish the screening sample size from the enrolled sample size; a table may be helpful. For electronic survey studies involving online recruitment and survey completion: consider how you will set controls on how many people will join your study.*

This is a pilot study. As such, our main study objectives are to pilot the intervention materials, and study procedures. Given that we will recruit from currently enrolled participants in the Project SafeSchools cohort study, our sample size is limited to the number of participants

meeting eligibility criteria within the ongoing study. Projecting our final enrollment for Project SafeSchools (IRB #14911), we anticipate 264 adult/caregivers in Project SafeSchools. Based on +CiM/HSP study inclusion criteria described below and using the baseline data of current Project SafeSchools participants, we estimate that 44% of adults/caregivers and 10% of of the youth they report on in Project SafeSchools will qualify for inclusion in +CiM/HSP. Multiplying the total enrollment in Project SafeSchools by the percentage we expect to be eligible, leads to an estimated 118 adults and 26 youth eligible for participation.

Given the low number of youth eligible for enrollment, we utilized only adult caregiver enrollment in our power calculation. Power is calculated for the 118 potential adult participants. Before calculating power, we further adjusted this number by 20% to account for people declining participation which results in an estimated enrollment of 94 participants. After further accounting for a conservative 20% attrition rate, we end up with a final estimated sample size of ***N* = 75 adults**. With alpha = 0.05, power = 0.80, and equal allocation to each study arm, we estimate being able to detect a medium to large effect size of *d = 0*.66. Given the baseline standard deviation of depression and anxiety, we calculated the absolute group differences needed to achieve our minimum effect sizes for each outcome, which are displayed in the table below.

Table 1. Group Differences and Effect Size

		Group Difference when Effect Size = .66
CESDR-10 (SD = 6.4)		4.2
PROMIS (SD = 5.3)		3.5

C. *Does your study meet the NIH definition of "clinical trial": "***A research study in which one or more human subjects are prospectively assigned to one or more interventions** (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes"? *If yes, the study must be listed on clinicaltrials.gov, study personnel must complete GCP training, and federally funded studies must post consent forms on approved sites, like clinicaltrials.gov.*

Yes, registration on clinicaltrials.gov will be completed upon study approval.

IV. Participants:

Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care or who are wards of the State. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

A. **Inclusion Criteria:**

All participants must be parents/caregivers or index youth enrolled in Project SafeSchools.

Adult participants:

- Have elevated levels of mental distress as reported in a Project SafeSchools assessment.
- Agreement to be re-contacted for future research as part of their Project SafeSchools consent.
- Meeting symptom eligibility criteria as outlined in Table 2 at a screening assessment/baseline visit.

Youth participants:

- Are 11-16 years old
- Agreement from parent/caregiver to be re-contacted for future research from their Project SafeSchools consent form.
- Meeting symptom eligibility criteria based on a self-report screening assessment/baseline visit (outlined in Table 2).

For the inclusion criteria, mental distress is defined as meeting eligibility cutoff scores on the following instruments:

- Adult Participants
  - General Distress (Kessler)
  - Anxiety (PROMIS)
  - Depression (CESDR-10)
  - Recent Suicide Ideation (either CESDR-10 or Ideation Questionnaire)
- Youth Participants:
  - Depression (CESDR-10)
  - Emotional Problems (SDQ Emotional Problems Subscale)
  - Anxiety (SCARED)
  - Recent Ideation (Ideation question on CESDR-10 or ideation questionnaire)

Table 2. Mental Health Assessments and Eligibility Scores

Mental Health Assessment	**Scale**	**Cut Off Scores for Eligibility**
Adult screening tools		
Kessler (Stress)	0-24 scale	13+ is high risk
CESDR-10 (Depression)	0-30 scale	8+ is high risk
CESDR-10 (Recent Suicide Ideation)	0-4	1+ is high risk
PROMIS (Anxiety)	8-40 scale	17+ is high risk
Caregiver report screening tools*		
SDQ (Emotional symptoms)	0-10 scale	5+ is high risk
SCARED (Anxiety)	0 - 82 scale	25+ is high risk
Suicide Ideation	0-4	4 is high risk
Youth self-report		
CESDR-10 (Depression)	0- 30 scale	8+ is high risk
CESDR-10 (Recent Suicide Ideation)	0-4	1+ is high risk
SDQ (Emotional symptoms)	0 – 10 scale	6+ is high risk
SCARED (Anxiety)	0 - 82 scale	25+ is high Risk

*These cutoff scores are consistent with the mental health alerts through Project SafeSchools. If a caregiver reports the youth to be at risk of mental distress, the youth will proceed to be screened based on self-report.

Please note that it is not a requirement that both the adult caregiver and their child have elevated mental health risk in order to be eligible to participate in this study. The intervention and all data collection are done at an individual level not on a dyad basis.

B. **Exclusion Criteria:**
Inability to cognitively complete interventions and assessments.

About the White Mountain Apache Tribe
The White Mountain Apache Tribe (WMAT) resides in eastern Arizona on the Fort Apache Indian Reservation. There are approximately 15,500 tribal members who live within the 1.6-million-acre land base. JHCAIH has a 30+ year track record working with the WMAT to build frugal public health solutions that can scale to other low-income, underserved communities.

A reflection of the dire needs of many reservation-based populations, there is significant poverty among the White Mountain Apache: 61% of the population over 16 years old are either "Not in Labor Force" or unemployed. The median household income is $14,496, and 87% live below the federal poverty line. Fewer than half of Apaches older than 25 years of age have graduated high school, and 4-year college graduation, while increasing, remains less than 10%. Apache youth have extreme needs. Over half (54%) of Apache tribal members are below age 25, compared to approximately 35% of the overall U.S. population. Challenges brought on by historical trauma and related environmental risks significantly impact Apache youth's life course. Their psychosocial, educational and health disparities include high rates of school dropout, unintended teen pregnancy, and premature death from suicide, motor vehicle deaths, and substance misuse.

About the Navajo Nation
There are approximately 175,000 people living on the Navajo Nation, and 33% of all tribal members are under the age of 18. The average household size on the Navajo Nation is 3.5 persons. Married couple families make up 39% of households, and 26% of households are headed by single mothers. 14.7% of households on the Navajo Nation are multi-generational, and the median household income for the Navajo Nation is $27,389. Poverty rates on the Navajo Nation (38%) are more than twice the poverty rate in Arizona (15%). Almost half (44%) of youth <18 years are living in poverty. Navajo people face similar health disparities as those living on the Fort Apache Indian Reservation.

***NOTE**: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. Check "yes" to the HIPAA question in the PHIRST application.*

V. Study Procedures:

In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear. If you will collaborate with other institutions or organizations, or plan to subcontract JHSPH responsibilities to others, make clear their responsibilities in the Study Oversight section of this document. Be aware that all recipients of federal funding for non-exempt human subjects research must have a Federal Wide Assurance (FWA), which is a promise to comply with human subjects research regulations.

*If the JHSPH will serve as **data coordinating center**, indicate in the sections below which procedures JHSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section.*
If your study will develop in phases, address each item below by phase.

A. **Recruitment Process:**

1. *Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and their qualifications*.

   Study staff approaching potential participants will be trained to mastery in the study protocol and consent certified by a Project Coordinator, Site Team Lead, or Site Supervisor prior to performing recruitment or informed consent. We will conduct a virtual or in-person training using the JHBSPH field training guides for data collectors for all study staff or people approaching potential participants if they have not already completed this training. All study staff approaching potential participants will have been trained in safe conduction of human subjects research (CITI), HIPAA, and Good Clinical Practices in research and will hold corresponding valid certificates prior to engaging in any recruitment activities. In addition, study staff have been working on IRB No. 14911 already, and most have an existing relationship with potential participants for this research study. Any new study staff who come on board as part of this protocol will be trained in the same way as existing study staff and will "shadow" more experienced study staff members prior to engaging in solo study activities. This will prevent study participants from feeling like they are receiving a "cold call" from the research team.

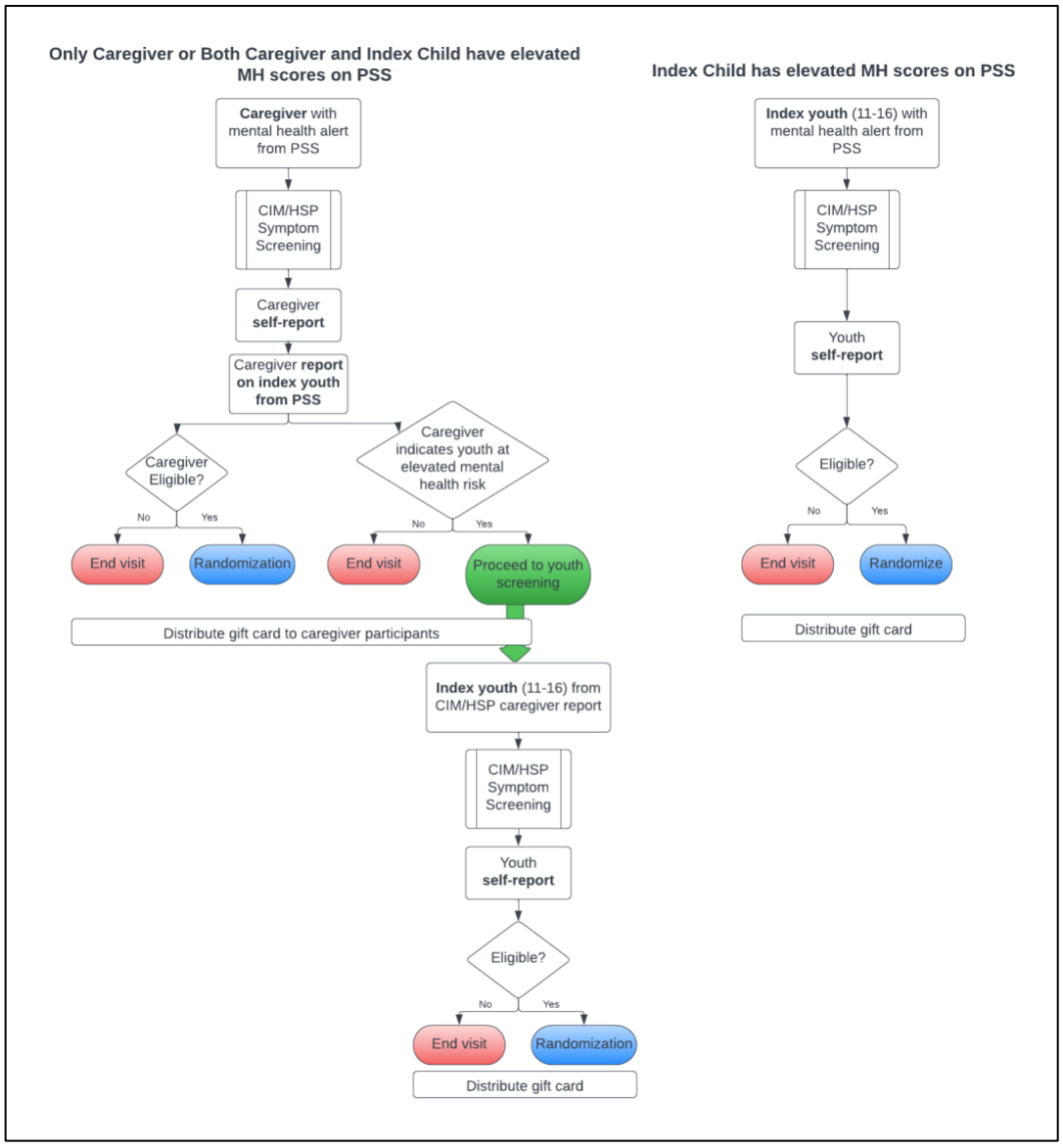
   Potential participants will be initially identified by use of existing mental health data collected as part of the Project SafeSchools assessments (IRB No.: 14911). Only caregivers and their youth with elevated mental health scores as indicated by standardized cutoff scores on symptom measures of anxiety, depression, emotional symptoms (youth only), and suicidal ideation (Table 2) and who consented to be contacted about future research as part of their consent provided for Project SafeSchools will be approached for participation in this study. Potentially eligible parent/caregiver participants will be contacted by phone or via an in-person visit to the participant's home by trained study staff to inform them about the study and assess their interest in participating. Study staff will tell potential participant about the study using the recruitment script. If unable to make contact initially, staff will attempt to contact the potential participant until the person can be reached and either agrees to or declines to participate or until staff have attempted to contact the potential participant 8 times, whichever comes first. Parents/caregivers must be contacted first before approaching the youth about participation in the study. If a person declines participation, they will not be contacted again. Potential participant status and attempted contacts will be recorded in REDCap to ensure protocol compliance. Agreement or declining to participate in the research study will never be disclosed.

   When a Project SafeSchools study staff team member first connects with the potential participant, they will describe the study and assess their interest in participating. If the potential participant is interested and eligible, their existing contact information will be checked for accuracy or new contact information will be recorded if needed (e.g., in the case the youth participant has different contact information from their caregiver). Then they will proceed to consent during the same visit or at a subsequent visit (within 1-2 days). If a separate time for consent is preferred by the potential participant, Project SafeSchools study staff will then re-contact the individual to obtain consent. Adult participants will have the option to complete consent and parent permission in one of three ways: 1) via a link to an online consent, 2) over the phone with a Project SafeSchools study staff team member, or 3) in-person at an agreed-upon time via tablet or on paper. Youth assent will only be conducted in-person or over the phone. Regardless of which method of consent/parent

permission/assent is used, study staff will record the date of consent in REDCap as part of the participant's record. The consent will include a consent for symptom screening and acknowledgement that if their symptoms do not meet the criteria, they will not be eligible for the pilot +CiM/HSP study but, if a parent/caregiver, will continue to be enrolled in the Project SafeSchools cohort study. Youth who are not eligible to participate after symptom screening will be thanked for their time, and their participation will end.

Eligibility screening is detailed in Figure 1. For screening, all adult participants (who had a mental health alert as part of PSS) will self-report on their own mental health and report on their youth's mental health if the youth is between the ages of 11-16. If the adult's screening instruments indicate eligibility, they will proceed to the remainder of the self-report baseline assessment. If the adult participant reports their child is at elevated risk of mental distress, they will be approached for parental permission at the end of the baseline assessment. If the parent provides permission, the youth will then be contacted to proceed with assent and screening/baseline as appropriate. Parents/caregivers of potential youth participants whose parents are not enrolled in +CiM/HSP, but who do have a mental health alert from Project SafeSchools, will be approached directly for permission. If permission is obtained, the youth will then be approached for assent and screening/baseline as appropriate.

Figure 1. Flow chart of screening process (next page)



2. *Address any <u>privacy</u> issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks*.

   Maintaining confidentiality is of the utmost concern. All staff will be trained in the conduct of human subjects research prior to starting any research activities. No identifiable information will be retained unless the person appears to be eligible and remains interested in the study. Ongoing supervision will assure rigorous compliance is maintained, including confidentiality. In addition, research staff engaging in recruitment will have training in the importance of confidentiality in AI/AN communities particularly with health care research that includes mental health assessments.

B. **<u>Consent Process</u>**:

1. *Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening*.

   a. *Who will obtain informed consent, and their qualifications*:

Consent, parental permission, and youth assent in this study will be obtained prior to any research-related participation. Study staff who have been trained by JHU will obtain informed consent from participants who do not give online consent. They will be trained in responsible conduct of human subjects research as a part of site training procedures. This will include training in the principle of respect for persons, protecting confidentiality, and the process of informed consent.

b. *How, where, and when the consent discussion(s) will occur*:

Informed consent and parental permission will be obtained by trained study staff in one of three ways: either online (adult participants only are eligible for this option), orally by phone, or in-person with documentation saved in REDCap. Minor assent will take place by phone or in person. Consent to participate will be obtained prior to the collection of any data. Online or verbal informed consent, permission, and assent will be obtained for all participants.

c. *The process for determining whether a potential participant meets eligibility criteria. If you will collect personally identifiable information for screening purposes, collect only data needed for this purpose and explain what will happen to the data for individuals who are not eligible*:

During recruitment, study staff will only approach those who were identified as being potentially eligible to participate in this study based on their mental health assessment cut off scores from the Project SafeSchools cohort study. This will be done as part Project SafeSchools existing safety response protocols which includes calling participants with these alerts and facilitating connections to resources in the community. At initial contact with potential participants, study staff will explain the study and ask if they are interested in participating. Potential participants or parents/caregivers of potentially eligible youth will be asked if they need to update their contact information (stored as part of Project SafeSchools) and provide separate contact information for their child if needed. This information is needed for screening purposes (if screening is done at a separate visit), but also to ensure delivery of intervention materials and possibly study assessments if they enroll. If they are ineligible or decide not to enroll, their contact information under this CiM/HSP protocol will be destroyed.

If a potential participant is interested, depending on preference, consent/assent will be administered during the same visit or scheduled for another day. If the person is not interested, they will be thanked for their time and continue to receive support for their mental health concerns and safety and continue to be enrolled in the Project SafeSchools cohort study. Study staff will document their decision in REDCap, and they will not be approached again about participation in +CiM/HSP.

As part of the consent process, individuals will consent to accessing their data collected in the Project SafeSchools cohort study. Eligibility screening for the +CiM/HSP study will occur after consent to participate and as part of the baseline assessment (Figure 1). An individual must score at or above the cut-off score on any of the mental health screening tools (see Table 2) to be included. If the person is determined to be ineligible after this screening, they will be notified by the study staff and informed that this ineligibility for +CiM/HSP study will in no way affect their participation in the Project SafeSchools study. If the participant is eligible for +CiM/HSP, they will continue with the rest of the assessment and other study activities.

This study is an individual intervention, not based on dyads. Only those caregivers and youth with elevated mental health scores at screening will participate. A parent/caregiver and youth can participate without the other being enrolled.

d. *Whether you will obtain a signature from the participant or will use an oral consent process*:

We will use an online or oral consent/permission/assent process due to COVID and to protect privacy.

e. *Whether you will obtain a legally authorized representative's signature for adults lacking capacity*:

N/A

f. *If children are included in the study, if and how you will obtain assent from them*:

Assent will be obtained following parent permission to be involved in the study.

g. If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision). If any of the children are "wards of the state", additional regulatory requirements will apply:

Parent permission will be obtained orally either over the phone or in-person prior to youth assent.

h. *If you are seeking a waiver of informed consent or assent, the justification for this request*:

N/A

i. *Whether you will include a witness to the consent process and why*:

N/A

j. *If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials*:

N/A

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

Table 3. Country and Languages for Consent

Country	Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.)	Languages
U.S.A	Adult Consent Documents, Parental Permission, Youth Assent	English

C. **Study Implementation**:

1. *Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate*.

Following consent/assent and screening, participants will be block randomized (with blocking on age [e.g., caregiver vs. youth] and gender) by REDCap into either the comparison group (coping plan with two follow-up check-ins) or the intervention group (coping plan with two follow-up check-ins and culturally adapted Caring Contacts). All participants, regardless of group, will receive up three COVID-19 safety text messages/postcards. These messages will be sent at approximately 45-, 60-, and 75-days post-enrollment and cover the following topics: respect and protection for others during the ongoing pandemic, compassion towards others by wearing a mask if necessary and getting tested if appropriate and protecting yourself and others by staying up to date on vaccination and boosters. See Table 4 for a summary of intervention activities by group.

Table 4. Intervention activities by study group

Intervention Activities	M1				M2				M3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
All Participants (est. N = 137)												
Coping Plan Intervention	X											
Follow-up check ins	X	X										
COVID-19 Prevention Messages							X		X		X	
Caring Contacts participants (est. N = 69)												
Caring messages			X	X	X	X		X		X		X

i. All Participants: Coping Plan, follow-up check-ins, and COVID-19 messages est. *N* = 137

All study participants will receive a one-hour support visit (either by phone or in-person) from a study staff person to develop an individualized plan for coping with life's challenges. This modified safety plan will include information on who and where they can get help during tough times or when they are feeling down. It will also include some ways they can work through these challenges. The plan is an adapted version of the evidence-based Safety Planning Intervention (described in background section) and was designed to address the underlying risk of suicide and other mental health stress as well. A couple of days after this visit, a study staff person will call the participant to check-in on how things are going and make additional community referrals. A second check-in will occur the following week. All staff will receive additional training on completing a coping plan. Finally, all study participants will receive up to 3 COVID-19 safety messages. Participants may choose to receive caring messages by text message or paper postcard sent in the mail. Participants with text messages that bounce back to the Johns Hopkins team at any point during the study will be automatically switched to receiving postcard messages until an updated phone number is provided.

ii. Intervention Group ONLY: Caring Contacts est. *N* = 69

The intervention group will also receive up to 7 culturally responsive caring messages from the research team over a period of three months.

iii. Assessments

During the screening/baseline assessment and all subsequent assessments (30 days [±10], and 90 days [±10] after screening/baseline) all study participants will be contacted to participate in a self-administered survey via REDCap. Paper copies of the questionnaire, along with a scoring manual for study staff to use at baseline for symptom screening), will be available as back-up. This survey will include the mental health measures described below, as well as questions regarding the participants' attitudes and beliefs about COVID-19 prevention strategies (e.g., masking when appropriate, visiting a health care provider), testing, and vaccination. The domains and survey items for

parents/caregivers are listed in Table 5 and the domains and survey items for youth are listed in Table 6 below.

A username and password are required to access the REDCap system. Study staff will launch the assessments on a tablet or, if preferred, via a link to the survey that participants can access from their phone or personal computer/tablet. If needed forms can be printed and provided on paper, but data must be entered into REDCap as soon as the staff member has it back at the office. Tablets will be synced daily with REDCap using a secure Wi-Fi connection available at the study site. For the assessments completed via phone, staff will read the questions to the participant. Study staff are trained to provide additional information to clarify questions as necessary. If in-person, the study staff member will provide the tablet to the participant so that they can complete the assessment via self-report. If done on paper, the study staff will provide the paper packet. They will be available if questions should arise. Data collected through REDCap is automatically stored on a Johns Hopkins HIPAA compliant, secure server. Direct data entry into REDCap eliminates the need for separate data entry and coding. Any data that is collected via hard copy will be entered into REDCap. Once entered into REDCap, for any participant who scores above pre-established cutoffs on mental health instruments or indicates suicide risk (see Safety Monitoring section), a notification will appear on the tablet to the interviewer to proceed with safety procedures. An additional email alert to the site supervisor, PI and study coordinator will also occur when the data is uploaded to the server to promote communication and allow for timely follow-up. Data will be downloaded from REDCap as a complete database into de-identified Excel and Stata files that will be stored on Johns Hopkins' HIPAA compliant, secure server. Data will be retained until the end of study analysis or three years after the final participants exit the program, whichever comes first.

Each assessment timepoint include the following scales or items by type of respondent:

Table 5. Parent/Caregiver Time points and Measures

Domain	**Instrument**	**Items**	**Baseline/ Screener**	**30 Days**	**90 Days**	**Included in PSS secondary data analysis**
Adult Self-Report						
Mental Health Outcome Domains						
General Distress	Kessler	11	X	X	X	X
Depression Symptoms	CESDR-10	10	X	X	X	X
Anxiety Symptoms	PROMIS	8	X	X	X	X
Intermediary Outcome Domains/Program Feedback						
Social Connectedness	Selected questions from Awareness of Social Connectedness and Multicultural Mastery	7	X	X	X	X

Coping Behaviors	Selected Items from Brief COPE Scale	9	X	X	X	
Mental Health Service Knowledge, Access, and Use	Internally developed questionnaire	4	X	X	X	
COVID Behavior Attitudes	Internally developed questionnaire	6	X	X	X	
Intervention Implementation and Feedback	Internally developed questionnaire	15			X	
Parent/Caregiver Report on Child (Only if child is eligible/enrolled)						
Mental Health Outcome Domains						
Emotional symptoms	SDQ Emotional Subscale	5	X	X	X	X
Anxiety	SCARED	41	X	X	X	X
Self-Harm	Internally developed questionnaire	2	X	X	X	X
Intermediary Outcome Domains/Program Feedback						
Coping Behaviors	Selected Items from Brief COPE Scale	9	X	X	X	
Youth Resilience	Selected Questions from Child/Youth Resilience Scale	4	X	X	X	X
Mental Health Service Knowledge, Access, and Use	Internally developed questionnaire	4	X	X	X	

Domain	**Instrument**	**Items**	**Baseline/Screener**	**30 Days**	**90 Days**
Mental Health Outcome Domains					
Emotional Symptoms	SDQ Emotional Subscale	5	X	X	X
Depression	CESDR-10	10	X	X	X
Anxiety	SCARED	41	X	X	X
Intermediary Outcome Domains/Program Feedback					
Coping Behaviors	Selected Items from Brief COPE Scale	9	X	X	X

Knowledge of Coping Strategies	Internally developed question	1	X	X	X
Youth Resilience	Selected Questions from Child/Youth Resilience Scale	4	X	X	X
COVID Behavior Attitudes	Internally developed questionnaire	6	X	X	X
Intervention Implementation/ Feedback	Internally developed questionnaire	13			X

Table 6. Youth Self-Report Time points and Measures

a. All participants (i.e., parent/caregivers & youth)

COVID-19 Behavior Attitudes: This is an internally developed, 6-item inventory on participants' attitudes towards specific COVID-19 related behaviors, including masking, testing, and vaccinations.

Coping Behaviors: Coping behaviors are measured by a subset of questions from the brief COPE inventory. 8 items out of 28 items in the brief COPE that are relevant to the intervention, focusing on coping behaviors that could be modified through the coping plan. An additional 1 item has been added to assess participant's perceived knowledge of coping strategies.[19]

Mental Health Service Knowledge, Access, and Use: This is an internally developed questionnaire that includes 4 items on knowledge of mental health services in the community, use of services in the previous 30 days, and difficulties accessing services.

Intervention Feedback: This is an internally developed questionnaire which includes 15 items focused on the implementation and participant perceptions of both the text-messaging and coping plan interventions.

b. Parent/Caregiver

Kessler: The Kessler Psychological Distress Scale is a six item self-report questionnaire that gathers information about a person's psychological distress. It uses a 0-24 scale, where a score of 13+ is considered high risk.[21]

Center for Epidemiologic Studies Depression Scale Revised (CESDR-10): The CESDR-10 is a revised 10 item self-report questionnaire which measures depressive symptoms in adult general populations. It utilizes a 0-30 scale, in which a score of 8+ is considered high risk. The CESDR-10 also has one item that ask about recent suicide ideation.[22]

Patient-Reported Outcome Measurement Information System (PROMIS): PROMIS is an eight-statement survey that measures emotional distress due to anxiety that has been experienced over the previous seven days. It uses a five-point Likert scale, 1 indicating 'never' to 5 indicating 'always'. The survey is scored from 8-40 with a score of 17+ indicating high risk.[23]

Social Connectedness: A subset of questions from two scales, the Awareness of Connectedness and Multicultural Mastery Scale, were selected to measure social connectedness. The Awareness of Connectedness a 12-item scale focused developed for use with Native American populations based on the interrelated welfare of the individual, one's family, one's community, and the natural environment. The community subscale, consisting of 4 items, is included in this study. The Multicultural Mastery scale measures problem solving through the participant's community and social network. Three items from the Multicultural Mastery scale relevant to the intervention are included.[18]

c. Youth

Strengths and Difficulties Questionnaire (SDQ) (Parent-Report and Youth Self-Report): SDQ is a self-report questionnaire that can be used with youth ages 11-17. The emotional symptoms subscale is used in the questionnaire, which consists of 5 items. The questionnaire uses a 0-10 scale where a score of 5+ is considered high risk.[24]

Center for Epidemiologic Studies Depression Scale Revised (CESDR-10) (Youth Self-Report): The CESDR-10 is a revised 10 item self-report questionnaire which measures depressive symptoms in adult general populations. It utilizes a 0-30 scale, in which a score of 8+ is considered high risk. The CESDR-10 also has one item that ask about recent suicide ideation.[22]

Screen for Child Anxiety Related Emotional Disorders (SCARED) (Parent-Report and Youth Self-Report): The youth self-report SCARED survey can be used with those aged 8-18 years. It includes 41 items and five scales which measure somatic/panic, general anxiety, separation anxiety, social phobia, and school phobia. SCARED uses a 0-82 scale where a score of 25+ is high risk.[25]

Youth Resilience: Two items related to social connections from the Child/Youth Resilience Scale were selected to assess youth resilience.[20]

2. *Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place*.

The number and type of study visits are described in Table 7 below.

Table 7. Number and type of study contacts by intervention component and study arm

Study Arm	Activity	Number of Contacts	Estimated Length of Time	Where/How
Coping plans only (Comparison Group)	Coping plan	1	1 hour	In person, over the phone
	Check-in calls/visits	2	15-30 minutes each (total time: 30 minutes-1 hour)	In person, over the phone
	REDCap Survey	3	15-30 minutes (total time: 45 minutes-1.5 hours)	In person, over the phone, email, text
	COVID Prevention Messages	3	N/A	Text message, ground mail

Caring contacts group (Intervention group)	Coping Plan	1	1 hour	In person, over the phone
	Check-in calls/visits	2	15-30 minutes each (total time: 30 minutes-1 hour)	In person, over the phone
	Caring Contacts	7	N/A	Text message, ground mail
	REDCap Survey	3	15-30 minutes (total time: 45 minutes-1.5 hours)	In person, over the phone, email
	COVID Prevention Messages	3	N/A	Text message, ground mail

3. *Describe the expected duration of the study from the perspective of the individual participant and duration overall*.

   Caregivers and youth will be enrolled in this study for three months.

4. *Provide a brief data analysis plan and a description of variables to be derived.*

   Analysis for all aims: Are planned statistical analysis will focus on the parent/caregiver surveys, given anticipation that sample sizes will be higher for this group. However, we will analyze the youth self-report descriptively. For adult outcomes, we will examine change over time on outcome measures and differences on these trajectories by study arm (Aim 1) or by timepoint (Aim 2). Additional analyses may also occur depending on guidance from our Community Advisory Boards. Every effort will be made to generate complete data; however, inevitably some data will be missing, and the methods recommended by Schafer and Graham (2002) will be used to evaluate missing data assumptions and guide the analyses. Based on the amount of missing data and evidence for a Missing At Random versus Missing Not At Random missing data mechanism, missingness will be addressed. The missing data approach will be finalized before the outcome analysis. Our analytic plan will also leverage data collected as part of their participation in the Project SafeSchools cohort study (see section XI for details). This will serve as a historical control comparison period for Aim 2, as well as provide a better understanding of longer-term impact of the interventions.

5. *Answer the following **if they are relevant to your study design***:

   A. *If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.*

      Participants will be block randomized with blocking on age (e.g., caregiver vs. youth) and gender. A randomization table will be created in a statistical software (e.g., Stata, SAS, R) and incorporated into REDCap. Randomization and assignment of intervention or control groups will occur following consent by a study team member. The study team member will only need to select the randomization option within the participant's study REDCap form for randomization to occur.

   B. *If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about who will collect the specimen, the volume (ml) and frequency of collection, how the specimen will be used, stored, identified, and disposed of when the study is over. If specimens will be collected*

for use in future research (beyond this study), complete the "Biospecimen Repository" section below.

N/A

C. *If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or another large dataset. Address returning unanticipated incidental genetic findings to study participants.*

N/A

D. *If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.*

N/A

E. *If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.).* ***For clinical tests of human biospecimens, no results may be returned unless completed in a certified lab.*** *Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants*.

N/A

F. *If your study involves medical, pharmaceutical, or other therapeutic intervention, provide the following information:*

a. *Will the study staff be blind to participant intervention status*?

No blinding will occur.

b. *Will participants receive standard care or have current therapy stopped*?

Yes, participants will be able to access the current standard of care; participants will be able to access all medical, mental, or behavioral health services they desire. During any study visit, research staff can direct individuals to appropriate sources of information as needed.

c. *Will you use a placebo or non-treatment group, and is that justifiable*?

The comparison group will receive an evidence-based tool (coping plan + two additional check-in calls or visits) and information on community support services (e.g., tribal behavioral health).

d. *Explain when you may remove a participant from the study*.

We will not remove any participants from the study.

e. *What happens to participants on a study in which there is a medical intervention when the study ends*? *Will participants continue to have access to the study intervention? What happens if they leave the study early?*

N/A

f. *Describe the process for referring participants to care outside the study, if needed*.

Participants in this study have been identified as being at risk for more severe mental health concerns including anxiety, depression, and suicidal ideation or past behavior. As such, study participants will be allowed and encouraged to access any available outside mental or behavioral health care. All study staff are knowledgeable about resources in the community that are available for any medical, mental, or behavioral health need. As part of our other studies, we have compiled a list of these resources in each site, and regularly update this resource list to ensure accurate information. There are several assessments in the assessment instruments we are using battery that have validated cutoff scores indicating the individual might be at risk for more severe mental health concerns. If an adult participant responds in a way that meets the cutoff score for themselves or indicates through their responses that their youth meets the cutoff score, the participant will receive a referral to local mental and behavioral health services and be encouraged to contact those services as soon as possible. If a participant asks for or requires additional outside care, study staff will work with their site manager and PIs (if necessary) to provide information to the participant on how to access that care.

VI. Data Custody, Management, Security, and Confidentiality Protections: *Data security and management plans must meet institutional standards. If you need assistance, contact jhsph_cybersecurity@jhu.edu.*
Investigators are responsible for ensuring the security of data from the time of collection, through any transfers from one system to another, analysis, sharing, storage, and ultimate archiving and disposal. The questions below seek to elicit your plans for these protections. Feel free to add information.

1. Data Sources: Identify the source(s) of data.

☒ Participant/Parent-Guardian/Legally Authorized Representative
☐ JHM Medical Records (from Epic)
Note for JHM Data Users Only: *Please complete the* ***Data Trust Risk Tiers Calculator*** *available on the Applications and Forms page on the JHSPH IRB website:* https://tinyurl.com/2p96md3s *and upload a copy of the documents to the "Miscellaneous- Other" section of your PHIRST application.*

In addition, review the ***Data Protection Attestation for Research and/or Healthcare Operations*** *at:* https://tinyurl.com/yszfkuur *and certify your attestation of compliance to those requirements.*
☐ **I certify my attestation of compliance to JHM Data Protection Requirements**
☐ Non-JHM Medical Records
☐ Outside Data Pprovider (CMS, National Death Index, Insurance Co., etc.)
☒ Other Existing Records (*please specify*):
Project SafeSchools data records

2. Data Content: Will you collect, use, and/or record personal identifiers about study participants for any purpose? Please look at the list of identifiers in Question 3 to help answer this question. **Note: Limited Data Sets (including dates, ages, and zip codes) are considered to be "identifiable".**

☒ Yes: Continue with Question 3
☐ No: Skip to Question 6

3. Data Identification: Identify the Personally Identifiable Information (PII)/Protected Health Information (PHI)

you will access/collect by checking the box(es) below for "Recruitment" and "Study Data" needs.

Recruitment	Study Data	PII/PHI to be Accessed/Collected
☒	☐	Name, signature, initials or other identifiable code
☒	☐	Geographic identifier (address, GPS location, etc.)
☒	☐	Dates (birth, death, clinical service, discharge, etc.)
☒	☐	Contact information (phone number, email address, etc.)
☐	☐	Identification numbers (SSN, driver's license, passport, etc.)
☐	☐	Health records identifiers (medical record #, insurance plan, etc.)
☐	☐	Text of clinical record notes
☐	☐	Device identifiers (implants, etc.)
☐	☐	Internet identifiers (IP address, social media accounts, etc.)
☐	☐	Biometric identifiers (fingerprints, retinal scan, voice print, etc.)
☐	☐	Audio Recordings
☐	☐	Video or full-face photographic images
☐	☐	Genomic / Genetic data
☐	☐	Other identifiers (*list here*):

4. Identifiers: If you have checked any of the boxes above, how will you protect personal identifiers?

☐ Will delete all identifiers (explain **when** you will delete identifiers):
☒ Will separate identifiers from analytic data and will store the link/code. Please explain where you will store the link/code: The link between study IDs and personal identifiers will only be maintained in a secure REDCap database.
☐ Will use a method to make it harder to connect the data with the study participant (jiggering date, use other methods to obfuscate, etc.). *Please explain:*

5. Data Transit Plans and Protections: Identifiable data may transfer, sometimes with multiple steps, from mechanisms for collection to storage. For example, participants may complete a web-based survey, which is then downloaded to a storage platform. Briefly identify these steps and the protections for each step (including encryption used at each step).

☐ Will delete all identifiers prior to transfer.

☒ Will separate identifiers from analytic data and will store the link/code prior to transfer. *Please explain*

where you will store link/code: De-identified survey data collected via paper document will be entered into the REDCap database by a trained member of the study team where it will be linked to the participants identifiers. De-identified survey data collected via tablet or email link will be connected back to the participants REDCap profile instantaneously or when in range of WiFi.

☐ Other (*please specify*):

6. Device(s) used for <u>data collection</u>: Identify the computing device(s) being used for identifiable data receipt/collection. Check all that apply.

☒ Provided or managed by JHSPH IT

☐ Study-provided, and not managed by JHSPH IT. These must include the following protective controls:

- Data encrypted while "at rest" (on a storage device)
- Security patches and updates are routinely or automatically applied
- Devices have access controls so that:
  - Each person accessing the device is uniquely identified (username)
  - Passwords are sufficiently strong to prevent compromise
  - All access is logged and recorded
  - Unauthorized access is prevented
- Approved access list is reviewed periodically for correctness

☐ Other (*please specify*):

7. Data Collection: Describe the format of data received/collected. Check all that apply.

☒ Paper/Hard Copy (must be secured in transit and placed in a secure cabinet/room)

☐ Audio recording

☐ Video recording

☒ Received directly by research team member and entered into file/database

☐ Mobile or Web App (custom developed). *Review guidance and provide attestation of compliance*

☐ Mobile or Web App (purchased). *Specify product and version*:

☒ Online survey. *Specify mechanism/platform*: REDCap

☐ 3rd party collector (*please specify*):

☐ Existing data shared with JHSPH by data provider via electronic access/transfer

☐ Duplicate and backup copies will be secured with same rigor as original data

☐ Other (*please specify*):

8. Devices/Platforms used for Analysis, Storage, Processing: Identify where the identifiable or de-identified data

will be analyzed/stored. Check all that apply.

☒ Pre-approved storage and analysis platforms managed by JH/JHSPH for which security and risk mitigation measures are known.
Identify pre-approved storage platform(s) being used:
JHM Preferred:
☒ JH SAFE Desktop ☐ JH PMAP

Other Approved Platforms:
☒ JH One Drive/JHSPH OneDrive ☐ JH IT-Managed Network Storage ☐ JHM/JHSPH Qualtrics
☐ JHSPH HPCC ☐ JHSPH SharePoint ☐ JHSPH Shares ☒ JHU REDCap
☐ MARCC-Secure Environment

X Platform(s) not managed by JH/JHSPH, not pre-approved, and require a risk assessment review from JHSPH Data Security (*please describe*): We will need to upload first name and phone numbers of enrolled and randomized participants into TextIt directly to allow for MMS. The Twilio/REDcap integration does not allow sending of MMS which is integral to the intervention. Thus, Twillio is being phased out as we switch to TextIt due to inability of Twilio to send MMS.

- Describe risk mitigation measures that are in place: TextIt is a cloud-based service to generate texting campaigns and chatbots. TextIt hosts with Amazon Web Services, and all data is stored solely in the United States. TextIt servers are protected by firewalls, and all access to those servers is permitted only through encrypted channels that are FIPS-140-2 compliant.

  Our TextIt subscription is password-protected and requires two-factor authentication. Only study management team members have access to the username and password that is associated with the account. This information is kept on password-protected computers and not saved anywhere else.

Note: The following are examples of platforms/storage solutions that are **not pre-approved to store identifiable information** and require a risk assessment from JHSPH Data Security:

- Other solutions not managed by IT@JH, e.g., commercial cloud storage (Box, Dropbox, iCloud, personal OneDrive, Google Drive, Amazon storage, etc.)
- JHU Independent Departmental Servers
- Local Computer owned by JH
- Other computers or devices owned/managed by study team members and used for other than secure web access
- USB/Portable data storage device

10. Access to Data and Access Controls: How will you ensure that only authorized individuals can access the data? What access controls will you put into place to ensure that only authorized individuals may access and use the data. (For example, OneDrive *guidance* illustrates how to share files with "people you specify". *JHSPH-Shares* addresses providing permissions to individual people.) Check all that apply. Note: If you need assistance implementing secure access controls, contact *jhsph_cybersecurity@jhu.edu.*

☐ Will provide access to data in accordance with OneDrive/JHSPH-Shares guidance posted on JHU IT websites
☒ Will use secure access controls to limit access to individual-level data
☒ Will use secure access controls to provide other researchers controlled access only to aggregated study data

11. Data Sharing: Clarify if data are to be shared externally with third parties, including sponsors and other investigators, and whether only aggregated data will be shared, or if you will share individual-level data. Describe sharing and protection plans for that sharing, including the proposed use of data agreements.

Consider the following:

- *Information about your data sharing in the consent forms*
- *Information about data sharing laws in the country where data will be collected, and if they limit sharing, how you will comply with those limitations?*
- *Whether data will be shared in aggregate only, or individual level data*
- *Whether you plan to make the data publicly available, and in what form.*

☐ Will not share data with outside investigators
☒ Will share aggregated data only
☐ Will share individual-level data without identifiers
☐ Will deposit data into an existing data repository for future research (e*xplain*):
☐ Other sharing information:

12. Duration and Destruction: Explain how long data will be retained and the plan for eventual return, deidentification or destruction of data, including moving data to an archive.

Because this study is connected to and utilizes some of the data associated with the Project SafeSchools study (IRB No.: 14911) a longitudinal study, PII will be maintained for up to 10 years after the completion of the study to allow for possible follow-up/ future collaboration. Consent forms will be maintained for three years after the completion of research per 45 CFR 46.117.

A. Certificate of Confidentiality:

All NIH studies include Certificate of Confidentiality (C of C) protections with the grant; the consent form must include the C of C language provided in our template. Other funders may obtain C of C protections through NIH. (https://grants.nih.gov/policy/humansubjects/coc.htm)

Does the study have Certificate of Confidentiality protections? Yes ☒ No ☐

VII. Risks of the Study:

A. *Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. Include risks beyond individuals to include the study population as a group and community risks. Ensure that the risks described in the consent documents are consistent with the risks outlined in the research plan*.

We anticipate minimal risk associated with this study. The main burden is the amount of time it will take to complete the assessments. Participants may also be uncomfortable completing the assessments which will ask about some potentially sensitive topics including their own mental health distress. Additionally, there is a risk of a breach of confidentiality.

Respondents who are distressed may reveal suicidal intent during the intervention and/or follow-up survey. Although this is not a direct risk of participation in this study it is important to have a plan in place. A detailed suicide response plan (Suicide Risk Safety Procedures) is included in 'Miscellaneous Documents'.

B. *Describe steps you will take to mitigate or minimize each of the risks described above. Include a description of your efforts to arrange for care or referral for participants who may need it.*

1. **Institutional Review Board** at Johns Hopkins, Health Board review with White Mountain Apache, review process by Navajo Nation Human Research Review Board. The study research plan, study instruments, and consent forms will be reviewed by an IRB at Johns Hopkins School of Public Health and will be reviewed by appropriate tribal authorities.

2. **Training of all study staff.** All senior staff have already been trained and certified in human subjects confidentiality and HIPAA compliance; and safe conduct of research during COVID-19. Initial training in all study procedures will be conducted by the study team virtually and/or in person as allowed by the local sites. Investigators will provide weekly Zoom supervision. There will be daily supervision provided at each local site by site managers. All levels of training and supervision will target that study staff satisfactorily provide the intervention components and administer the survey.

3. **Informed consent/assent.** We will provide potential respondents a clear opportunity to understand the study objectives and procedures, to assess study risks and benefits, and, verbally, to give or decline consent freely and without pressure or penalty.

4. **Mental health referrals.** The assessments for the proposed study are the same as what is currently being used in the associated Project SafeSchools cohort study for adults and caregiver reports on youth. As such, we will continue to use the mental health referral procedures that have already been approved for that study. Briefly, if adult participants respond on the CESDR-10, or PROMIS anxiety measure (parent/caregiver participants) in a way that meets or exceeds the cutoff score or indicate their child (parent/caregiver participants) meets the standard cutoffs on the SDQ, or SCARED, will receive a referral to local mental health services on the Reservation and be encouraged to contact these

services. Similarly, if any youth self-reports on the CESDR-10, SDQ or SCARED we will use the same referral processes. We have strong relationships with local services in each site, which include services for both adults and youth and including ongoing collaboration with mental health and suicide response teams on both the Fort Apache Indian Reservation and Navajo Nation. If a participant asks or requires urgent mental health care, study staff will inform the site manager and PIs (if necessary) and they will follow up with the study participant to further assess and provide information to the participant on how to access appropriate care. All study team members will have completed Psychological First Aid training.

5. **Suicide Risk Plan.** An imminent risk procedure was developed by JHU for previous studies to ensure triage and access to emergency care for suicidal individuals. Risk will be gauged by immediately scoring the suicide-related questions. Questions from the CESDR-10 that indicate recent suicide ideation (i.e., in the last two weeks) for adults and youth will be identified and flagged in REDCap and an automatic alert setting for these questions will automatically alert senior members of the study team. Study team members have all received Applied Suicide Intervention Skills Training (ASIST) and can respond in crisis situations. If the study team receives an alert for suicidal ideation based on a participant completing the survey instruments online (adults only; youth are not allowed to complete surveys online) after working hours, a text will be sent to them that contains the National Suicide Prevention hotline number and crisis text line. Study staff will follow up with them within 24 hours to provide additional support and resources. To make it possible to send the text message, we will enable Twilio integration in REDcap. See the 'Miscellaneous Documents' for the details of this Suicide Risk Safety Procedures.

6. **Staff training and familiarity with local context.** We have attempted to minimize these risks by employing Native paraprofessionals who are trained in active listening, problem-solving, maintaining confidentiality, assessing worsening of symptoms, providing support, and other relevant procedures, including basic relaxation techniques to ensure each participant's comfort and well-being. If any participant becomes distressed during the surveys or interviews, a break will be provided, or the survey/interview will be stopped, and the research staff will work with the participant to reduce the participant's distress using basic relaxation techniques. If the participant's distress is not able to be addressed by these approaches, the Research Program Assistants will ask if the participant wishes to address the distress in another manner and will facilitate the participant's request when possible. In addition, Research staff can enlist the site supervisors at each site to talk with the participant via phone and facilitate referrals if necessary.

7. **Data Storage and Protection.** No unique identifiers will be collected in data collection forms or handwritten notes

8. **Adverse Event Monitoring.** Study staff, a supervisor, or community mental health specialists on staff will assist participants in obtaining additional services for adverse events. The PI will recommend premature study termination based on defined safety procedures.

C. *Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an "anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?*

In general, we do not expect any adverse reaction to the study activities.

D. *Describe the research burden for participants, including time, inconvenience, invasion of privacy in the home, out of pocket costs, etc*.

Participant burden is described as follows: Study activities will be provided via an in-person visit, phone calls, text messages and/or mailed postcards. In person visits will take place either at school, at the Johns Hopkins office, in a private space in the community, or at the person's home. Youth/caregiver participants will have up to two study visits (one for consent and coping skills planning) each lasting approximately 1 hour and two follow-up phone calls or in-person check-ins each lasting around 30 minutes for a total active study time of 3 hours.

Assessments will be done either virtually (via phone, Zoom, or REDCap survey sent directly to a participant's smart phone), in-person at a safe distance and while following COVID-19 safety protocols depending on the participant's preference, or by a self-administered paper packet dropped off by a study team member. There are 3 assessments for each participant type, which should take 15-30 minutes each to complete. Thus, total time anticipated for data collection is a maximum of 1.5 hours.

All study participants are expected to spend a maximum of 4.5 hours total participating in this research study. For participants who are not eligible to continue their participation after symptom screening, their maximum total time spent participating in the study should not exceed 1.5 hours (consent visit and baseline screening).

E. Describe how participant privacy, and if relevant – family privacy - will be protected during data collection if sensitive questions are included in interviews, or if study visits occur in the home setting.

Every effort will be made to ensure privacy and confidentiality to the participant. All surveys will be conducted virtually, or in-person at a safe distance and while following COVID-19 safety protocols or be self-report. If conducted over the phone or administered through the web, study staff will ask the participant to use headphones and/or find a private location in their home. If done through paper and pencil, the participant will be reminded to fill it out and place it in a sealed envelope to send back to the study team via packet pick up. If done in-person at school, study staff will allow the person to fill it out in private on a tablet or on paper but stay close by in case of questions.

VIII. Direct Personal and Social Benefits:

A. Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).

The study provides culturally adapted evidence-based interventions to those with elevated mental health distress. This will likely reduce distress for those enrolled.

B. Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

This study will allow us to understand what impact brief and cultural adapted interventions have on AI/AN communities who are disproportionately affected by anxiety, depression, and suicidal thoughts and behaviors. Adapting a low cost, evidence-based practices such as safety planning and Caring Contacts may help with reduction of symptoms as well as providing those with known mental and behavioral health concerns with support in accessing appropriate services.

IX. Payment or Token of Appreciation:

A. Do you plan to provide a non-monetary token of appreciation (food, soap, tea, chlorine tablets, etc.) to study participants? If no payment is provided, the JHSPH IRB strongly encourages providing such tokens. If yes, please describe below.

There are no current plans to provide participants in this study with non-monetary tokens of appreciation.

B. *If you plan to provide a monetary payment, describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain*.

Participants in the pilot study will receive compensation for each assessment they complete in the form of a gift card. The payment structure is included here:

Questionnaire Timepoint	**Gift Card Amount**
Parents/Caregivers	
Baseline screening	$15
1 month post-enrollment	$20
3 months post-enrollment	$25
Youth	
Baseline screening	$10
1 month post-enrollment	$10
3 months post-enrollment	$20

C. Include the possible total remuneration and any consequences for not completing all phases of the research.

Parent participants will receive a $15 gift card for completing the eligibility screening/baseline assessment and youth will receive a $10 gift card. Parent/caregivers who continue after the eligibility screening/baseline will receive a $20 gift card for the questionnaire they complete after 30 days post enrollment, and a $25 gift card for completing the questionnaire 90 days post enrollment. Thus, parents/caregivers may receive up to $60 total in gift cards throughout the study. In addition to the $10 gift card for completing the eligibility screening/baseline, youth participants will also receive a $10 gift card for completing the questionnaire 30 days post enrollment and a $20 gift card for completing the questionnaire 90 days post enrollment. Thus, youth may receive up to $40 total in gift cards throughout the study.

X. Study Management:

A. Oversight Plan:

1. *Describe how the study will be implemented. List all parties, including collaborators and subcontractors, who will be "engaged" in the human subjects research project and their roles.*

Dr. Haroz will oversee all aspects of the study and will provide regular check-ins with the Co-Is, Sr. Project Coordinator, Project Coordinator(s), Site Team Leads, Site Managers, and Research Program Assistants. Dr. Haroz assumes primary responsibility for the study, including protection of human participants and assurance of regulatory compliance. Dr. Joshuaa Allison-Burbank will serve as the Community PI for Navajo Nation and as a Co-I on the project. Dr. Allison-Burbank is responsible for liaising with the community and presenting to local IRBs as well as working with site-based staff and helping to oversee management of the study. Ms. Allison Ingalls, MPH, will serve as the Sr. Project Coordinator. Both Ms. Renae Begay and Ms. Shannon Archuleta will serve as project coordinators based in the Southwest at study sites. They will facilitate day to day management of the study and provide support for REDCap and other project coordination activities. Ms. Francene Larzelere, MS, MS, PhD candidate (WMAT), will serve as the WMAT Site Manager. Mr. Paul Rebman will support data collection, cleaning, and analysis.

2. *What are the qualifications of study personnel implementing the project*?

   Emily Haroz, PhD, Associate Professor, Director of Mental and Behavioral Health Research Methods, JHCAIH, has a master's in clinical psychology, is a psychiatric epidemiologist and implementation scientist by training, and has worked with Apache and Navajo partners for over 4.5 years. She has specific expertise for leading the evaluation project.

   Francene Larzelere, MS, doctoral candidate (WMAT), Sr. Research Associate, has worked as a behavioral interventionist for JHCAIH for over 20 years, oversees all the WMAT behavioral health studies, and is the Center's primary liaison to the WMAT Tribal Council and Health Board.

   Allison Ingalls, MPH, Senior Research Associate, has worked for JHCAIH for over 10 years, has extensive experience and expertise in project management and will help support all study coordination.

   Joshuaa Allison-Burbank, PhD, CCC-SLP, Assistant Scientist, is a Diné and Acoma Pueblo speech language pathologist and developmental scientist interested in culturally responsive assessment, neurodevelopment of Indigenous children and how stress and trauma impact developmental trajectory.

   Renae Begay, MPA, Research Associate, is Diné and acts as the Project Safe Schools coordinator for the Center's Navajo Nation sites. She has extensive experience in community building and public school-based quality improvement programs.

   Paul Rebman, MPH, Research Associate, has experience working with communities which lack access to needed resources here and abroad. He will oversee the design and implementation of data collection in REDCap as well as aid in data analysis.

   Shannon Archuleta, MPH, Research Associate, has experience in providing research support from development to implementation and dissemination. She will aid in program implementation at the Fort Apache site.

3. *How will non-professional personnel (data collectors) involved with the data collection and analysis be trained in human subjects research ethical protections? (Use the JHSPH Ethics Field Training Guide available on the JHSPH IRB website. If* the study is a clinical trial, consider using the JHSPH Good Clinical Practice (GCP) For Social and Behavioral Research Field Guide).

   All study staff are trained and certified in human subjects confidentiality, HIPAA compliancy and GCP for Social and Behavioral Research as part of their onboarding process when hired; and safe conduct of research during COVID-19. Initial training in all study procedures will be conducted by the PI virtually and include role-playing. Investigators will provide weekly Zoom supervision. There will be daily supervision provided at each local site by site team leads, with additional in-person oversight by co-Is. All levels of training and supervision will target that study staff satisfactorily administer the intervention and survey.

4. *If the JHSPH PI is responsible for data collection and will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team*.

Investigators will provide weekly Zoom supervision. There will be daily supervision provided at the local site by site team leads and/or site supervisors, who will be in regular contact with the study manager and PIs.

B. **Protocol Compliance and Recordkeeping:**
Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. (For assistance, contact: housecalls@jhu.edu *Please provide information about study oversight to ensure compliance with IRB approval and regulatory and institutional requirements. If the study team does not follow study procedure, what is your plan for reporting protocol non-compliance?*

All study staff will be managed and supervised by a local site team lead and/or site supervisor. This will involve regular debriefings with staff to review activities and identify any issues or challenges. In addition, consent and data collection forms and notes will be reviewed by the local site manager and study staff to ensure that study protocols are being properly adhered to. Any paper consent forms, data collection forms, and handwritten notes will be stored in a locked filing cabinet on site that will only be accessible by the local site managers. No data or forms will be accessed or allowed to be taken out of the room directly by anyone other than them. The site team lead/supervisor takes responsibility for collecting data records (forms and notes) from staff and ensuring that files are destroyed once the study is complete. The site team lead/supervisor will be in close communication with Dr. Haroz to ensure these processes are adhered to. In the case of non-compliance, local site managers will inform Dr. Haroz who will determine whether the non-compliance is serious and when to report it to the IRB.

C. **Safety Monitoring:**

1. *Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role and what is that person's specific charge?*

   The PI, Dr. Haroz, assumes responsibility for the safety of study participants. Study staff will be trained to monitor for the safety of study participants and report any concerns immediately to the site manager and the PI. Study staff will be trained in human subject's research and will be required to complete the CITI ethics module prior to any interaction with participants or study data. Certificates of human subject's completion will be kept on file at the Center for American Indian Health's office in Baltimore. A list of community resources will be provided with each assessment visit – either verbally by the study staff administering the survey or by paper.

   At the end of any assessment administered, a notification will appear to the research program assistant if suicide risk (e.g., recent ideation and/or recent attempt) is indicated, the research program assistants will then respond in a graduated fashion based on the safety protocol outlined in 'Miscellaneous documents'.

2. *If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following*:

   a. *The DSMB membership, affiliation, and expertise*.
   N/A

   b. *The charge or charter to the DSMB*.
   N/A

   c. *Plans for providing DSMB reports to the IRB*.
   N/A

3. *Describe plans for interim analysis and stopping rules, if any*.
   None.

D. **Reporting Unanticipated Problems/Adverse Events (AEs) to the IRB (*all studies must complete this section*)**:

*NOTE: The IRB does not require PROMPT reporting of all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**.*
***Anticipated** AEs may be reported with the Continuing Review/Progress Report.*

Describe your plan for reporting to the JHSPH IRB, local IRBs, and (if applicable) to the sponsor. Include your plan for government-mandated reporting of child abuse or illegal activity.

Study staff will immediately alert the site manager and PIs in the event of an adverse event or unanticipated problem. The PI, Dr. Haroz, and the Sr. Project Coordinator will report serious adverse events to all relevant IRBs if it is unanticipated, poses a risk of harm to participants or others, and is related to the study. If there is any suspected harm to self, others, or abuse reported during a study visit, the study staff will immediately report this information to the site manager and PI. The PI and the site manager will report this to appropriate Tribal or Law Enforcement Authorities. With experience from previous studies with the White Mountain Apache and Navajo Nation communities, the study team is knowledgeable of how to report this type of event without revealing study participation.

E. **Other IRBs/Ethics Review Boards:**
*If other IRBs will review the research, provide the name of each IRB/ethics review board and its Federal Wide Assurance number, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances). **For federally funded studies, subrecipients MUST have a Federal Wide Assurance (FWA) number from the OHRP. The IRB overseeing the subrecipient should be registered with the OHRP. The JHSPH IRB will not have oversight responsibility for international subrecipients, and generally will not oversee data collection at external U.S. institutions Please contact jhsph.irboffice@jhu.edu with questions.***

Table 8. Navajo Nation IRB Information

Non-JHSPH IRB/REC	FWA Number
Navajo Nation Human Research Review Board Dr. Rebecca Izzo-Manymules; (928) 697-2525; rizzo_mm@hotmail.com	00008894

F. **"Engaged" in Human Subjects Research:**
For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

N/A

Insert collaborator names and FWA numbers, if available. Note who will be "engaged" in human subjects research by filling in the following table:

Table 9. Grant and Federal Wide Assurance

	JHSPH		
For federally funded studies, collaborators' FWA	00000287		
Primary Grant/Contract Recipient	x		
Grant/Contract Subrecipient			
Hiring Data Collectors			
Training Data Collectors			
Obtaining Informed Consent and/or Identifiable Data			
Accessing/Analyzing Identifiable Data			
Overseeing storage, access and use of biospecimens			

COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY:

XI. Secondary Data Analysis of Existing Data:

A. **Study Design:**

1. *Describe your study design and methods. The study design must relate to your stated aims/objectives.*

   The study design and aims are the same as for the application described above (see Section I). Secondary data analysis will consist of linking participant information to data collected as part of the Project SafeSchools study (IRB No.: 14911).

2. *Provide an estimated sample size and an explanation for that number*.

   Based on data collected so far, we have estimated 45% of adult caregivers (based on their mental health scores at baseline) and 7% of youth (based on both their parent-reported mental health scores at baselines and their age) in the Project SafeSchools study are eligible for participation. We project a total enrollment of N = 264 adult caregivers in the Project SafeSchools study who are also reporting on an index child, leading to an estimated N = 118 caregivers and N = 26 youth ages 11-16 (index children in the Project SafeSchools cohort study) who will have reported (either self- or parent-report) mental distress or recent suicidal ideation that places them in the risk category for more severe disorder and who will be eligible to join the +CiM/HSP study.

3. *Provide a brief data analysis plan and a description of variables to be derived.*

   Data from Project SafeSchools (IRB No.: 14911) will be used to help in estimating the stability of psychosocial functioning prior to interventions as well as serve as a longer-term follow-up of the impact of interventions over time. For our primary Aim, estimating the effectiveness of +CiM/HSP, we will used mixed-effects models to compare symptom scores across arms with our main outcome time point to be analyzed based on the Wave 3 outcome time point in Project SafeSchools, estimated to be approximately 3-6 months after enrollment into +CiM/HSP. For Aim 2, we will use a within subjects design to measure differences in symptoms prior to starting the +CiM/HSP intervention components compared to after completion of the intervention components using the Project Safe Schools Wave 1, 2, and 3 data collection timepoints. This analysis will focus on the measures that are common to both the +CiM/HSP protocol and the Project SafeSchools data (e.g.,

Adult self-report on depression and anxiety symptoms and caregiver report on strengths and difficulties, resilience items).

B. **Participants:**

1. *Describe the subjects who provided the original data and the population from which they were drawn.*

   Study subjects are all youth ages 11-16 or adult caregivers over the age of 18 that either attend or have a student attending a school serving enrolled tribal members of the White Mountain Apache Tribe or the Navajo Nation.

   Note: If you are receiving, accessing, or using data from a U.S. health care provider, the need for HIPAA review is likely. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. If either of these conditions is met, check "yes" to the HIPAA question in the PHIRST application.

2. *If you plan to analyze human specimens or genetic/genomic data, provide details about the source of those specimens and whether they were collected using an informed consent document. If yes, explain whether your proposed use is "consistent with" the scope of the original consent, if it potentially introduces new analyses beyond the scope of the original consent, and/or if it introduces new sensitive topics (HIV/STDs, mental health, addiction) or cultural/community issues that may be controversial.*

   N/A

3. *Explain whether (and how) you plan to return results to the participants either individually or as a group*.

   The results will be disseminated to all study participants through partnerships and presentations at board of director meetings, school board meetings, and public forums as deemed appropriate by local collaborators. Only de-identified data and analyzed in aggregate will be shared.

XII. Oversight Plan for Student-Initiated Studies:

A. *For student-initiated studies, explain how the PI will monitor the student's adherence to the IRB-approved research plan, such as communication frequency and form, training, reporting requirements, and anticipated time frame for the research. Describe who will have direct oversight of the student for international studies if the PI will not personally be located at the study site, and their qualifications.*

   N/A

B. *What is the data custody plan for student-initiated research? (Note: Students may not take identifiable information with them when they leave the institution.)*

   N/A

XIII. Creation of a Biospecimen Repository:

Explain the source of the biospecimens, if not described above, and what kinds of specimens will be retained over time. Clarify whether the specimens will be obtained specifically for repository purposes, or will be obtained as part of the core study and then retained in a repository.

A. Describe where the biospecimens will be stored and who will be responsible for them.

N/A

B. Describe how long the biospecimens will be stored, and what will happen at the end of that period.

N/A

C. *Explain whether the biospecimens will be shared with other investigators, inside and outside of JHU, how the decision to share will be made, and by whom. Include your plans, if any, for commercial use. Also explain how downstream use of the specimen will be managed, and what will happen to left-over specimens*.

N/A

D. Describe whether future research using the biospecimens will include specimen derivation and processing (cell lines, DNA/RNA, etc.), genomic analyses, or any other work which could increase risk to participants. Explain what additional protections will be provided to participants.

N/A

E. If future research could yield unanticipated incidental findings (e.g., an unexpected finding with potential health importance that is not one of the aims of the study) for a participant, do you intend to disclose those findings to the study participant? Please explain your position.

N/A

F. *Explain whether the specimens will be identifiable, and if so, how they will be coded, who will have access to the code, and whether the biospecimens will be shared in linked (identifiable) form*.

N/A

G. Explain whether the repository will have Certificate of Confidentiality protections.

N/A

H. Explain whether a participant will be able to withdraw consent to use a biospecimen, and how the repository will handle a consent withdrawal request.

N/A

I. Describe data and/or specimen use agreements that will be required of users. Provide a copy of any usage agreement that you plan to execute with investigators who obtain biospecimens from you.

N/A

XIV. <u>Data Coordinating Center</u>:

Complete if JHSPH serves as the Data Coordinating Center.

A. How will the study procedures be developed?

N/A

B. *How will the study documents that require IRB approval at each local site be developed? Will there be some sort of steering or equivalent committee that will provide central review and approval of study documents, or will template consent forms, recruitment materials, data collection forms, etc. be developed by and provided to the local sites by the coordinating center without external review?*

N/A

C. *Will each local clinical site be overseen by its own IRB with an FWA, or will a Single IRB review the study? State whether the coordinating center will collect IRB approvals and renewals from the clinical centers; if not, explain why.*

N/A

D. *How will the coordinating center provide each local site with the most recent version of the protocol and other study documents? What will be the process for requesting that these updates be approved by local clinical center IRBs?*

N/A

E. *What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?*

N/A

F. *What is the process for reporting and evaluating protocol events and deviations from the local sites? Who has overall responsibility for overseeing subject safety: the investigators at the recruitment site, the Coordinating Center, the Steering Committee, or a Data and Safety Monitoring Board (DSMB)? Is there a DSMB that will evaluate these reports and provide summaries of safety information to all the reviewing IRBs, including the coordinating center IRB? Please note that if there is a DSMB for the overall study, then the coordinating center PI does not have to report to the coordinating center IRB each individual adverse event/problem event that is submitted by the local site PIs.*

N/A

G. *Some FDA regulated studies have different AE reporting criteria than that required by the IRB (IRB Policy No. 103.06). How will you reconcile the different requirements, and who is responsible for this reconciliation?*

N/A

H. *Who is responsible for compliance with the study protocol and procedures and how will the compliance of the local sites be monitored and reviewed? How will issues with compliance be remedied?*

N/A

XV. Drug Products, Vitamins, Food and Dietary Supplements:

Complete this section if your study involves a drug, botanical, food, dietary supplement, or other product that will be applied, inhaled, ingested or otherwise absorbed by the study participants. If you will be administering drugs, please upload the product information.

N/A

A. *List the name(s) of the study product(s), and the manufacturer/source of each product.*

N/A

Name of Study Product	Manufacturer/Source

B. *List each study product by name and indicate its approved/not approved status.*

N/A

Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name)	Cleared for Use at Local Study Site

C. *If your study product has an Investigational New Drug (IND) application through the U.S. Food and Drug Administration, provide the IND number, and the Investigators Brochure.*

N/A

Who will hold the IND?

N/A

D. *If your study product is a marketed drug, provide the package inserts or other product information. If the study product WILL NOT be used for its approved indication, dose, population, and route of administration, provide a detailed rationale justifying the off-label use of the study product.*

N/A

E. *If the study product does not require FDA approval (e.g., dietary supplements, botanicals, products not subject to the U.S. FDA, etc.), provide safety information (as applicable) and a certificate of analysis.*

N/A

A. *Explain who will be responsible for drug management and supply, labeling, dispensing, documentation, and recordkeeping. Complete and upload into PHIRST the Drug Data Sheet available on the JHSPH IRB website at www.jhsph.edu/irb.*

N/A

B. *What drug monitoring and/or regulatory oversight will be provided as part of the study? Please describe.*

N/A

XVI. Medical Devices:

*Complete this section if your study will involve an approved or investigational medical device (**diagnostic**, non-significant risk, significant risk).*

A. List the name(s) of the study product(s), the manufacturer/source of each product, and whether or not it is powered (electric, battery). Provide product information. If it is electric, upload documentation of clinical engineering approval or its equivalent from a local authority, to ensure that the device is in good working order.

N/A

Name of Study Product	Manufacturer/Source	Powered?

B. List each study product by name and indicate its status as approved by a government authority or not approved.

N/A

Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name and approval information)	Not Approved

*C. If your investigational device is Exempt from the FDA IDE regulations, explain which section of the code applies to your device and why it meets the criteria provided. If it is a **diagnostic device**, provide pre-clinical information about the sensitivity and specificity of the test and the anticipated failure rate. If you plan to provide the results to participants or their physicians, justify doing so, and explain how those results will validated (or not) against the current "gold standard".*

N/A

D. If you believe the investigational device is not IDE exempt under 21CFR 812.2(c) but is a "Non-Significant Risk" device considered to have an approved IDE application, provide information from the manufacturer supporting that position.

N/A

E. If you are using an investigational device that is a Significant Risk Device, provide the IDE number given by the FDA, or if not under FDA jurisdiction, explain why it is appropriate to use this device in this study. Provide a description of the device and upload a picture or manufacturing schematics into PHIRST. Provide any other information relevant to a determination of its safety to be used for the purposes outlined in this research plan.

N/A

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